UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,335	09/22/2003	Francesco Borrelli	BORRELLI2A	8379

1444 7590 08/08/2006

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
O'HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,335	BORRELLI ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-19* is/are pending in the application.

4a) Of the above claim(s) *9-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *7-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/889,828.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/22/03 & 5/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 7-19 are pending in the instant application. Claims 7, 9-16 and 18 have been amended, claims 1-6 have been canceled and claim 19 has been added as requested by Applicant in the Paper filed May 31, 2006.

Election/Restrictions

2. Applicant's election with traverse of II in the reply filed on May 31, 2006 is acknowledged. The traversal is on the ground(s) that the anti-TNF antibodies, TNF-RI and TNF-RII are all considered TNF sequestering antagonists and that such a genus of TNF sequestering antagonists were previously examined together by the Examiner in parent application 09/889,828, and there should be no serious burden to do the same in the present application. This is not found persuasive because in parent application 09/899,828, the specific TNF antagonists were not searched, the method of treating and the correlation between TNF and endometriosis was searched. Because the method of treating TNF mediated endometriosis was novel and unobvious, any method of using a TNF antagonist for treatment of endometriosis was also novel and unobvious. However, the instant claims require a search of the different specific TNF antagonists, because the limitation in the claims of the pharmaceutical compositions as being for the treatment of endometriosis is not given patentable weight (see rejection under 35 USC § 102). Consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. These criteria were met in the restriction. Therefore, the different TNF antagonists would require separate searches, which would be an serious search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 7, 8 and 17-19 are currently under examination.

Priority

Priority

3. Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed, and also the status. See 37 CFR 1.78. The status of application 09/889,828 should be updated (now U.S. Patent No. 6,663,865).

Claim Objections

4. Claim 19 is objected to because of the following informalities: it depends from a canceled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5.1 Claims 7, 8 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Elliott et al., The Lancet, Vol. 344, No. 8930, Oct. 22, 1994, pages 1105-1110.

Claims 7, 8 and 17-19 encompass a pharmaceutical composition comprising a TNF antagonist which may be a sequestering or a signaling antagonist which is an anti-TNF antibody or fragment thereof and which may be a chimeric monoclonal or a humanized monoclonal antibody and a pharmaceutically acceptable carrier.

Infliximab, also known as Remicade, D2E7 or cA2, is a monoclonal chimeric humanized antibody comprising human contant and murine variable regions (PDR Electronic Library). Elliott et al. disclose using the antibody in a trial of patients with rheumatoid arthritis, in which the antibody was administered in a pharmaceutical composition comprising a pharmaceutically acceptable carrier (page 1106, *Study Infusions*). Therefore, Elliott et al. anticipates the claims. As discussed in the response to the restriction requirement, the limitation in the claims of the pharmaceutical compositions as being for the treatment of endometriosis is not given patentable weight. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new

function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.< See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

5.2 Claims 7, 8 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Salfeld et al., U.S. Patent No. 6090382, filing date Feb. 9, 1996.

The claims are discussed above. Salfeld et al. disclose and claim a pharmaceutical composition comprising Infliximab, also known as Remicade, D2E7 or cA2, a monoclonal chimeric humanized antibody comprising human contant and murine variable regions, and pharmaceutically acceptable carrier (claims 28 and 29). Therefore, Salfeld et al. anticipates the claims.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PRIMARY EXAMINER